

DATE MAILED: 07/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		09/518,297	LIM ET AL.
		Examin r	Art Unit
		Chih-Min Kam	1653
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status			
1)🛛	Responsive to communication(s) filed on 22 A	<u>pril 2002</u> .	
2a)⊠	This action is FINAL . 2b) ☐ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims			
4)⊠	Claim(s) 1-19 and 21-30 is/are pending in the	application.	
4	4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>1-19 and 21-30</u> is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement. Application Papers			
9) The specification is objected to by the Examiner.			
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12)☐ The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:			
1. Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) latent Application (PTO-152)
S. Patent and Tra	Idemark Office		

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DETAILED ACTION

Status of the Claims

1. Claims 1-19 and 21-30 are pending.

Applicants' amendment filed on April 22, 2002 (Paper No. 13) is acknowledged, and applicants' response has been fully considered. Claims 1, 11, 14, 18, 23-26 and 29-30 have been amended.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

- 2. The previous rejection of claims 1-19 and 21-30, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 5-7 in Paper No. 13.
- 3. The previous rejection of claims 1-19 and 21-30, under 35 U.S.C.112, second paragraph, regarding the term "in the vicinity of said DNA response element", "a DNA binding compound", "adeno-associated virus vector" or "from about.... to...", or, the sentence indicating the first nucleic acid construct contains DNA binding compound, or, antecedent basis on "said regulatory domain" and "an activator domain", is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 7-9 in Paper No. 13.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1, 3, 5, 16 and 17 under 35 U.S.C. 102(b) as being anticipated by Voet *et al.* (Biochemistry pages 854-856 and 868 (1990)) or Evans *et al.* (U. S. Patent 5,071,773), is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 9-12 in Paper No. 13.

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- 5. The previous rejection of claims 1, 3, 5 and 16-18 under 35 U.S.C. 102(b) as being anticipated by Gottesfeld *et al.* (Nature 387, 202-205 (1997)), is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 9-12 in Paper No. 13.
- 6. The previous rejection of claims 1, 3, 5 and 16-18 under 35 U.S.C. 102(a) as being anticipated by Dickinson *et al.* (Proc. Natl. Acad. Sci. USA 95, 12890-12895 (1998)), is withdrawn in view of applicants' amendment to the claim and applicants' response at pages 9-12 in Paper No. 13.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-19 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 and 21-30 are indefinite because of the use of the term "a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound". The term "a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element for binding to a DNA binding compound" renders the claim indefinite; it is unclear how a non-native compound binding sequence which is introduced to the DNA construct can be the same as the DNA binding element for a transcriptional regulatory protein. Claims 2-10, 12-17, 19 and

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21-30 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Conclusion

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.

Patent Examiner

July 8, 2002

KAREN COCHRANE CARLSON, PH.D

DDIMARY FYAMINER

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